

for sale, the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for diagnosing or treating leg trouble, menopausal difficulties, arthritis, poisons in the body, underactive or overactive organs, and fractures, which were the conditions for which they were orally represented by J. Vincent Reed, D.C., on 2-5-58.

**DISPOSITION:** On 5-19-58, J. Vincent Reed, D.C., claimant, filed an answer denying that the devices were misbranded as alleged in the libel, and on the same day filed a motion to dismiss the libel. The motion to dismiss was overruled on 6-24-58.

On 11-5-58, the Government filed written interrogatories which were served against the claimant. Subsequently, the Government filed a motion for order of default decree of condemnation for failure to answer the interrogatories. On 12-15-58, the claimant filed a second motion to dismiss the libel. The court, on 12-16-58, denied claimant's motion and denied also the Government's motion for default decree. The Government then filed a motion for order compelling an answer by the claimant to the written interrogatories. The court granted the motion on 12-30-58.

Thereafter, the Government and claimant having stipulated on additional facts, and having submitted the matter to the court for decision, the court, on 5-15-59, handed down findings of fact and conclusions of law to the effect that the leaflets accompanied and served to misbrand the devices. The court made no finding of misbranding under 502(f) (1).

On 5-21-59, judgment of condemnation was entered and the court ordered the devices to be delivered to the Food and Drug Administration.

#### DRUGS FOR VETERINARY USE

**5907. Medicated feed.** (F.D.C. No. 42903. S. No. 48-142 P.)

**QUANTITY:** 18 100-lb. bags at West Bridgewater, Mass.

**SHIPPED:** 2-13-59, by Dean & Lee, from Horseheads, N.Y.

**RESULTS OF INVESTIGATION:** The article was shipped in response to an order for a poultry feed containing 0.0125 percent sulfaquinoxaline.

Examination showed that the article delivered contained about 0.095 percent sulfaquinoxaline.

**LIBELED:** 3-25-59, Dist. Mass.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(b)—the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient; 502(f)—the labeling failed to bear (1) adequate directions for use and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of the user.

**DISPOSITION:** 5-4-59. Default—destruction.

**5908. Hexadin, Arsan Powder, and Weatol.** (F.D.C. No. 42927. S. Nos. 22-121/3 P.)

**QUANTITY:** 6 cases, 12 1-lb. jars each, and 4 25-lb. drums, of *Hexadin*, 10 8-oz. jars of *Arsan Powder*, and 2 1-gal. jars of *Weatol*, at Superior, Nebr.

**SHIPPED:** Between 4-14-58 and 10-10-58, from Kansas City, Kans., by Curts Laboratories.

**LABEL IN PART:** (Jar and drum) "Curts Hexadin with Dextrose 50% For oral administration in iodine deficiencies and in cases of actinomycosis in soft tissues that do not require surgery. Organic iodine compound . . . 5% (Hexamethylenetetramine tetraiodide 75.5% iodine) \* \* \* Directions \* \* \* Cattle and Horses \* \* \* Sheep and Swine."; (jar) "Curts Arsan Powder for swine dysentery or enteritis and/or a stomachic Sodium arsanilate . . . 26% \* \* \* Sodium phenolsulfonate, Iron pyrophosphate, Copper sulfate, Boric acid, Cobalt sulfate"; and (jar) "Curts Weatol Fish liver oil with alpha tocopherol acetate For oral administration as supplement in deficiencies of vitamins A, D and E. Daily dose Large animals \* \* \* Small animals."

**ACCOMPANYING LABELING:** Catalog entitled "Curts 1958 Products and Prices" and pamphlet entitled "Feature Drug Items Produced by Curts."

**LIBELED:** 4-9-59, Dist. Nebr.

**CHARGE:** 502(a)—(*Hexadin*) when shipped, the labeling, namely, the above-described catalog and pamphlet accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for the prevention of necrotic stomatitis and pneumonia, liver abscesses, calf diphtheria, keratitis, sterility and actinobacillosis in cattle, horses, sheep, and swine; (*Weatol*) the labeling, namely, the jar label and the above-described catalog and pamphlet accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for overcoming incidence of stillbirth and deformed offspring, and for increasing fertility of large and small animals; and the labeling of the *Weatol* also was misleading since it failed to reveal the amounts of vitamins A, D, and E present in the article, and also since the name "*Weatol*" suggested that the article contained a wheat germ oil base, when, in fact, it was labeled elsewhere as a fish liver oil base; and 502(f) (2)—(*Arsan Powder*) the article contained sodium arsanilate, and its labeling failed to warn that administration of the drug should be discontinued five days before slaughtering for human consumption to allow for elimination of the drug from the edible tissue.

**DISPOSITION:** 4-30-59. Default—destruction.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\***

**5909. Desarin tablets.** (F.D.C. No. 40575. S. Nos. 72-987/8 M.)

**QUANTITY:** 128 100-tablet btls. and 26 100-tablet btls. at Salt Lake City, Utah.

**SHIPPED:** 12-31-56 and 5-29-57, from St. Louis, Mo., by Victor M. Hermelin & Co.

**LABEL IN PART:** (128-tablet lot) "Desarin \* \* \* Estrogenic Substance \* \* \* Each tablet contains .625 mg. of estrogens in their naturally occurring water-soluble conjugated form \* \* \* Control No. 11-66"; or (26-tablet lot) "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form \* \* \* Control No. 5-66."

**RESULTS OF INVESTIGATION:** Analysis showed that the 128-tablet lot of the article contained 0.29 mg. of sodium estrone sulfate per tablet; and the 26-tablet lot of the article contained .91 mg. of sodium estrone sulfate per tablet.

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\*See also No. 5907.